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Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852



Docket No. 02N-0209 Request for Comment on First Amendment Issues. 67 FR45742, July 10, 2002

The lams Company appreciates the opportunity to submit this comment in response to the "Request for Comment on First Amendment Issues." The lams Company, which was founded in 1946 by Paul lams and acquired by Procter and Gamble in 1999, sells premium dog and cat foods in more than 70 countries around the world and is the leader in the premium pet food segment in the U.S.

FDA permits pet food companies to include on their product labels and labeling only a very limited number of truthful and non-misleading statements that describe a relationship between a food substance and the nutritional impact it has on a disease or health-related condition. Currently, for products sold in unrestricted commercial outlets, this class of claims, which can be referred to as "health-related statements," is limited to claims about urinary tract health, low magnesium and hairball prevention for feline diets. In deciding to allow these three claims, FDA/CVM addressed each on an *ad hoc* basis without any reference to an overarching, public, governing framework for permitting other such health-related statements in the future.

The absence of a public governing framework that would reliably allow pet food companies to efficiently include truthful and non-misleading health-related statements on their product labels and labeling operates as a *de facto* suppression by the FDA of truthful and non-misleading commercial speech in violation of the First Amendment rights of those companies. To remedy this situation, The lams Company urges FDA/CVM to implement a new and innovative mechanism that would allow pet food companies to include additional truthful and non-misleading heath-related statements on their product labels and labeling in a prompt and efficient manner. This new framework would complement rather than replace the existing structures for approving food additives and new animal drugs.

Under such a framework, pet food companies should be permitted to make use of truthful and non-misleading health-related statements without prior approval by the FDA/CVM. Instead, companies might be required to notify the FDA/CVM within 30 days of initiating the use of a new health-related statement on product labels or labeling and to provide FDA/CVM access to their supporting data upon request.

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